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Does Vitamin D improve markers of vascular health in type 2 diabetes?

Submission date
26/07/2005

Recruitment status
No longer recruiting

Registration date
12/09/2005

Overall study status
Completed

Last Edited
29/08/2017

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Low levels of vitamin D have been associated with higher blood pressure and a higher risk of heart attack and stroke. These are particular problems for people with diabetes, and it is possible that giving extra vitamin D to people with diabetes who have low vitamin D levels might help to protect against heart attacks and strokes. The aim of this study is to find out whether giving vitamin D can reduce blood pressure, improve measures of blood vessel health, and improve glucose levels in diabetes.

Who can participate?
Patients aged over 18 with type 2 diabetes and low levels of vitamin D

What does the study involve?
Participants' vitamin D levels are tested and if these are low, the health of their blood vessels is assessed by doing an ultrasound scan of their arm before and after blowing up a blood pressure cuff on their arm. Blood samples are also taken to measure a series of substances that vitamin D might affect, and their blood pressure is measured. Participants are then randomly allocated take either a single large dose of vitamin D or a matching dummy (placebo) dose with no vitamin D in it. This dose acts over a period of several weeks. All participants are asked to return to repeat all of the tests 8 weeks after this single dose.

What are the possible benefits and risks of participating?
Vitamin D is a safe treatment that has been used for decades. There is a small risk of increasing calcium levels in the blood, but these levels are monitored and anyone with high levels at the start of the study is not included.

Where is the study run from?
Ninewells Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2005 to June 2006

Who is funding the study?
Diabetes UK

Who is the main contact?
Dr Justine Davies
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
JUS004

Study information

Scientific Title
Does Vitamin D improve markers of vascular health in type 2 diabetes? A randomised controlled trial

Study objectives
That Vitamin D improves endothelial function, pulse wave velocity, insulin sensitivity and markers of renin-angiotensin system activation in type 2 diabetics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside (now East of Scotland) Research Ethics committee, 13/09/2005, ref: 05/S1401/125

Primary study design
Interventional

Study design

Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
100,000 units ergocalciferol versus placebo

Added 29/08/2017:
Intervention: 100,000 units oral Ergocalciferol (vitamin D2), given once at baseline
Comparator: Matching placebo, given once at baseline
Total duration of treatment and follow-up: 8 weeks for all treatment arms

Intervention Type
Supplement

Primary outcome(s)
Current primary outcome measures as of 29/08/2017:
Flow-mediated dilatation of the brachial artery in response to reactive hyperaemia, measured by ultrasound at baseline and 8 weeks

Previous primary outcome measures:
Change in flow mediated dilatation of the brachial artery

Key secondary outcome(s)
Current secondary outcome measures as of 29/08/2017:
1. 25-hydroxyvitamin D, serum calcium, serum phosphate, parathyroid hormone levels, measured by blood tests at baseline and 8 weeks
2. Glycosylated haemoglobin, insulin sensitivity using HOMA index, measured by blood tests at baseline and 8 weeks
3. Office blood pressure, measured by blood pressure cuff at baseline and 8 weeks
4. Renin and angiotensin levels, measured by blood tests at baseline and 8 weeks

Previous secondary outcome measures:
Pulse wave velocity, homeostasis model assessment (HOMA) index, renin, angiotensin, Vitamin D, parathyroid hormone (PTH)

Completion date
30/06/2006

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Vitamin D level <50 nmol/l

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Serum creatinine >200 µmol/l
2. Liver function tests >3 x upper limit of normal
3. Corrected calcium >2.55 mmol/l or <2.15 mmol/l
4. Metastatic malignancy
5. Unable to give informed consent

Date of first enrolment
01/11/2005

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK

Alternative Name(s)
The British Diabetic Association, DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available upon request from Dr Miles Witham (m.witham@dundee.ac.uk). Anonymised Individual participant data on all those randomised will be made available to bona fide researchers for non-commercial use, subject to sight of an analysis plan and subject to appropriate data sharing agreements and approval from the trial sponsor.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2008		Yes	No
Basic results		18/08/2017	29/08/2017	No	No